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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
LY, CHEYNE D	

ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 01/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/038,854	SPYTEK ET AL.	
	Examiner	Art Unit	
	Cheyne D Ly	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 June 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *42-47 and 49-63* is/are pending in the application.

4a) Of the above claim(s) *53,54,56,58,60 and 62* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *42-47,49-52,55,57,59,61 and 63* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *42-47 and 49-63* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *10/29/03; 5/24/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *Search Result 4*.

DETAILED ACTION

1. Applicants' arguments filed June 04, 2004 have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

2. The cancellation of claims 1-41 and 48, and withdrawal of claims 53, 54, 56, 58, 60, and 62 have been acknowledged.

3. It is noted that claims 53, 54, 56, 58, 60, and 62 have been inadvertently included as being examined in the 35 U.S.C. §112, Second Paragraph rejection in the previous Office Action. The withdrawal of claims 53, 54, 56, 58, 60, and 62 has been maintained.

4. Claims 42-47, 49-52, 55, 57, 59, 61, and 63, SEQ ID NO:37, are examined on the merits.

5. NON-FINAL OFFICE ACTION.

RESTRICTION REQUIREMENT

6. Applicant argues that "the claimed subject matter of claims 53, 54, 56, 58, 60, and 62 are sequences reasonably related to SEQ ID NO:38"; therefore, the search and examination of said claims would not unduly burden the Examiner. Applicant's argument has been fully considered and found to be unpersuasive. Applicant's argument of "[t]he only difference between the sequence of SEQ ID NO:38 and each of the sequences in claims 53, 54, 56, 58, 60, and 62 is that the latter contains a single amino acid change at a defined position as compared to the sequence of SEQ ID NO:38" further supports that the claimed subject matter of said claims are distinct from the elected SEQ ID NO:37 encoding the polypeptide of SEQ

ID NO:38. Further, the sequence of SEQ ID NO:38 does not comprise the sequences recited in claims 53, 54, 56, 58, 60, and 62; therefore, it would unduly burden the Office to search all the requested sequences. Due to the number of these requests made, it is practically impossible to accommodate all requests. The overwhelming number of sequences poses undue search burden when more than one nucleic acid sequence is elected, thus making the previous waiver to a complete search of all of the sequences of this instant application, effectively impossible to reasonably implement.

IDS

7. The information disclosure statements, field October 29, 2003 and May 24, 2004, respectively, have been considered. It is noted that document C287, field October 29, 2003, has been lined through because said document does not have a publication date.

CLAIM REJECTIONS - 35 U.S.C. § 112, SECOND PARAGRAPH

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

9. Claims 43, 45, and 51 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

RESPONSE TO ARGUMENTS

10. Applicant argues that the term "complement" is well known in the art; therefore, said term is not vague and indefinite. Applicant's citation page 865 from a textbook by Lehninger has not been considered due to the cited page not being in the instant application file. Specific to the citation of page 199, lines 5-9, of the instant application, the pointed to

support does not make "clear that the complement of a nucleotide sequence of a specific SEQ ID NO is intended to mean full length nucleotide sequence...defined by the SEQ ID NO." Further, the Examiner is not confusing the definition of a "complement" with the definition of "a complementary" nucleic acid. The instant specification including the pointed to support (page 199) does not specifically define the limitation of "complement", therefore, the limitation has been reasonably construed as any sequence (fragment or full length) capable of being complementary to the elected sequence. Therefore, Applicant's argument and pointed to support do not resolve the vague and indefinite issue as discussed below.

BASIS OF REJECTION

11. Specific to claim 45, the term "complement" causes said claim to be vague and indefinite because it is unclear what criteria are being used to determine a nucleic sequence is complementary to the sequence of SEQ ID NO. 37. Is a complement of 2 nucleotides sufficient to consider the claimed nucleotide sequence complementary? Clarification of the metes and bounds of the instant claims is required.

12. Specific to claims 43 and 51, the limitation of "the mature form of the polypeptide" causes said claims to be vague and indefinite because it is unclear whether the mature form is directed to a secreted protein or membrane protein. The specification on page 117 supports the vague and indefinite issue discussed above.

CLAIM REJECTIONS UNDER U.S.C. § 112, FIRST PARAGRAPH

13. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

LACK OF ENABLEMENT

14. Claims 42, 46, 47, 49, 50, 52, 55, 57, 59, 61, and 63 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

15. Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in Ex parte Forman, 230 USPQ 546 (BPAI 1986) and reiterated by the Court of Appeals in In re Wands, 8 USPQ2d 1400 at 1404 (CAFC 1988). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. The Board also stated that although the level of skill in molecular biology is high, the results of experiments in genetic engineering are unpredictable. While all of these factors are considered, a sufficient amount for a prima facie case is discussed below.

16. Claims 42 and 50 are not enabled because one of skill in the art cannot immediately recognize the embodiments which fail to permit translation of the polypeptide in an expression system. For example, Hatfield et al. (US 5,082,767 A) describes that despite the burgeoning knowledge of expression and recombinant DNA, significant obstacles remain when one attempts to express a foreign or synthetic gene in an organism. The translation of a

synthetic gene, even when coupled with a strong promoter, proceeds much more slowly than would be expected. And even when the gene is translated in a sufficiently efficient manner, the protein is often inactive or otherwise different in properties (failed embodiments) from the native protein. Therefore, one of skill in the art would not know how to predictably make the claimed invention without undue experimentation.

LACK OF WRITTEN DESCRIPTION

17. Claim 45 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

RESPONSE TO ARGUMENTS

18. Applicant argues that the term "complement" is well known in the art; therefore, said term is not vague and indefinite. Applicant's citation page 865 from a textbook by Lehninger has not been considered due to the cited page not being in the instant application file. Due to the instant specification does not specifically define the limitation of "complement", the limitation has been reasonably construed as any sequence (fragment or full length) capable of being complementary to the elected sequence. The instant specification does not provide written description basis that corresponds to the limitations embodied in claim 45. Therefore, claim 45 embodies sequences that do not meet the written description provision of 35 USC 112, first paragraph.

REJECTION RE-ITERATED

19. The specification discloses SEQ ID NO: 37 encoding the polypeptide of SEQ ID NO. 38. Claim 45 is directed to sequences that complement the sequence of SEQ ID NO: 37. Except of the sequence of SEQ ID NO: 37 encoding the polypeptide of SEQ ID NO. 38, the sequences that complement the sequence of SEQ ID NO: 37 do not meet the written description provision of 35 USC 112, first paragraph. The specification provides insufficient written description to support the genus encompassed by the claim.

> Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

20. With the exception of SEQ ID NO: 37, the skilled artisan cannot envision the detailed chemical structure of the encompassed polynucleotides and/or proteins, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. In Fiddes v. Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.

> University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that: ...To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." Lockwood v. American Airlines, Inc. , 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); In *re Gosteli* , 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by

describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood*, 107 F.3d at 1572, 41 USPQ2d at 1966.

21. Therefore, only SEQ ID NO: 37 but not the full breadth of the claim 45 meet the written description provision of 35 USC 112, first paragraph. The species specifically disclosed are not representative of the genus because the genus is highly variant. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC 112 is severable from its enablement provision. (See page 1115.)

CLAIM REJECTIONS - 35 USC § 102

22. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

23. Claims 42, 44-47, 49, 50, 52, 55, 57, 59, 61, and 63 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Oohashi et al. (May 1999).

24. It is noted that the limitation of "a polypeptide of SEQ ID NO:38" has been reasonably construed as any polynucleotide which encodes a dipeptide of SEQ ID NO:38.

25. Oohashi et al. discloses an isolated polynucleotide comprising/consisting of a nucleic acid sequence encoding a polypeptide of SEQ ID NO:38 (Result 4 and AB025412), as in instant claims 42, 44, and 50.

26. The isolated polynucleotide of Oohashi et al. comprises the complement of a polynucleotide of SEQ ID NO:37 at positions 50-52, as in instant claim 45.

27. The isolated polynucleotide of Oohashi et al. is expressed in an expression vector comprising a CMV promoter (page 565, Expression of Recombinant Ten-m1 and Ten-m1 fusion proteins §), as in instant claims 46, 47, and 49.

28. The polypeptide of Oohashi et al. encodes a serine at position 27, lysine at position 39, arginine at position 76, alanine at position 220, glutamine at position 236, and glycine at position 270 (see NCBI printout of AB025412), as in instant claims 52, 55, 57, 59, 61, and 63.

CONCLUSION

29. It is noted that Applicant's argument via pointed support to page 403, lines 21-30, has been found to be persuasive. The pointed to disclosure supports that the utility is for the nucleic acid in detection assays of nucleic acids. Therefore, the 35 U.S.C. §101, lack of utility rejection and the accompanied 35 U.S.C. 112, first paragraph, lack of enablement rejection, directed to the polynucleotide sequence of SEQ ID NO:37, have been withdrawn.

30. It is further noted that the encoding language is not being read as a limitation on the polypeptide. Additionally, the specification does not provide any specific or substantial utility support for the encoded peptide described by SEQ ID NO:38.

31. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

32. Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives

are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

33. For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

34. Any inquiry concerning this communication or earlier communications from the examiner should be directed to C. Dune Ly, whose telephone number is (571) 272-0716. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

35. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (571) 272-0722.

C. Dune Ly

1/9/05

MICHAEL P. WOODWARD
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